NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

On

"Combating the Opioid Crisis:
Helping Communities Balance Enforcement and Patient Safety"

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2123 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd., Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Burgess, Ranking Member Greene and the members of the Subcommittee on Health for your leadership and commitment to finding and implementing policy changes to address the opioid crisis. NACDS and our members remain committed to partnering with policymakers, law enforcement, and others to work on viable strategies to prevent prescription opioid diversion and abuse. Chain pharmacies engage daily in activities with the goal of preventing the diversion and abuse of all prescription medications, including opioids. We thank you for the opportunity to provide recommendations on policy changes to help curb the opioid crisis.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 22 countries. For more information, visit www.NACDS.org.

NACDS Key Policy Initiatives to Help Curb Prescription Opioid Abuse

As public health authorities have indicated, face-to-face interactions between pharmacists and patients have made pharmacists keenly aware of the extreme challenges and complexities associated with the opioid abuse epidemic.

Pharmacists and pharmacies fully understand that controlled substances are subject to abuse by a minority of individuals who improperly obtain controlled substance prescriptions from physicians and other prescribers. Pharmacists and pharmacies strive to treat medical conditions and ease patients' pain while simultaneously guarding against the abuse of controlled substances. The key is to guard against abuse without impeding our primary goal of assisting patients who need pharmacy services.

Based on our experiences, NACDS is pursuing four public policy solutions to complement pharmacy's collaboration with other stakeholders including healthcare professionals and law enforcement to address prescription opioid abuse in communities across the country.

I. Require Prescriptions to Be Issued Electronically

Chain pharmacy supports policies that promote the use of electronic prescribing to transmit prescription information between prescribers and pharmacists. For controlled substances in particular, use of this technology adds new dimensions of safety and security in the prescribing process. Data from self-reported drug abusers suggest that between 3% and 9%

of diverted opioid prescriptions are tied to forged prescriptions.[1,2] Electronic controlled substance prescriptions serve to reduce the likelihood of diversion in this manner, as electronic controlled substance prescriptions cannot be altered, cannot be copied, and are electronically trackable. Furthermore, the federal DEA rules for electronic controlled substances prescriptions establish strict security measures, such as two-factor authentication, that reduce the likelihood of fraudulent prescribing. Notably, the state of New York saw a 70% reduction in the rate of lost or stolen prescription forms after implementing its own mandatory electronic prescribing law.[3]

The rate of electronic prescribing has increased significantly in recent years. In 2008, there were about 68 million electronic prescriptions.[4] As of 2016, over 1.6 billion prescriptions were issued electronically, including approximately 45.3 million controlled substance prescriptions.[5] Still, there is room for further improvement, particularly with controlled substances prescriptions which lag behind in overall adoption rates. While 90% of all pharmacies are enabled to receive electronic prescriptions, only 17% of prescribers have systems that can send electronic prescriptions for controlled substances.[6]

To enhance healthcare providers' utilization of this technology and to foster prescriber adoption, chain pharmacy urges the adoption of policies to require that all prescriptions be issued electronically, with limited exceptions for situations in which issuing an electronic prescription may not be feasible. ***We support the Every Prescription Conveyed Securely Act (H.R. 3528), legislation that requires electronic prescribing for controlled substances in Medicare Part D. We thank Representative Mullin as an original cosponsor of this legislation and we ask that the Subcommittee work to pass this necessary legislation.***

II. Nationwide Prescription Drug Monitoring Program

NACDS supports the important role of prescription drug monitoring programs (PDMPs) in helping to prevent drug abuse and diversion. Over the years, PDMPs have been established throughout the country as tools to curb diversion and abuse of controlled substance prescriptions. At this time, nearly every state has implemented their own program designed to assist in the identification and prevention of drug abuse and diversion at the prescriber, pharmacy, and patient levels. However, there are significant variances across state programs, which altogether, impede optimal use of PDMPs to their fullest extent.

NACDS is calling upon stakeholders to work together to develop and implement a nationwide PDMP solution to harmonize state requirements for reporting and accessing PDMP data. Our goal is to establish one system with unified expectations for appropriate use of PDMP data by

[1] Rosenblum, Andrew, et al., "Prescription Opioid Abuse Among Enrollees into Methadone Maintenance Treatment," *Drug and Alcohol Dependence,* 90.1 (2007): 64-71.
[2] Inciardi, James A., et al., "The 'Black Box' of Prescription Drug Diversion," *Journal of Addictive Diseases*, 28.4 (2009): 332-347.
[3] Remarks of Anita Murray, Deputy Director, New York State Department of Health at the Harold Rogers Prescription Drug Monitoring Program National Meeting (September 6, 2017).
[4] Surescripts National Progress Report for 2012.
[5] Surescripts National Progress Report for 2016.
[6] Ibid.

prescribers, pharmacies, law enforcement, and others. Such a system would leverage electronic prescribing systems to provide timely, in-workflow analyses of real-time data with actionable point-of-care guidance for prescribers and dispensers. We urge the participation of policymakers, like the Office of the National Coordinator, other healthcare providers, law enforcement, and other stakeholders on this important initiative to create a national PDMP solution.

III. Take Back and Disposal of Consumer's Unused Controlled Substances

Chain pharmacies are committed to creating programs that provide patients with safe and effective ways to dispose of unwanted controlled substances. To this end, NACDS supports policies that accommodate pharmacy participation in a variety of DEA authorized options for controlled substance drug disposal programs. These options include, but are not limited to: take-back kiosks in pharmacies, mail-back envelopes made available by manufacturers or pharmacies, community drug take-back events hosted at pharmacies, in-home disposal products, take-back kiosks at law enforcement locations, and vouchers to patients to obtain mail-back envelopes from manufacturers or pharmacies. Of greatest importance, pharmacies must be offered a variety of program options, so that they can choose which consumer controlled substance drug disposal program best fits their patients' needs and is best suited for the community that they serve.

As highlighted in the above examples of drug disposal options, pharmacies alone are not the solution to the safe and effective disposal of unwanted controlled substances. Combating prescription drug abuse requires collaboration across the supply chain. Chain pharmacy seeks collaborative efforts, including working with manufacturers to help customers safely and effectively dispose of their unwanted opioid drugs. Accordingly, we support programs that require manufacturers to fund and make mail-back envelopes available to pharmacies to distribute to patients, upon request, when those patients fill opioid prescriptions. A program of manufacturer-funded mail-back envelopes for unused opioid drugs recognizes that the entire drug supply chain has a role in drug disposal.

Earlier this month, the FDA provided a policy document to the Energy and Commerce Committee in which FDA called upon manufacturers to establish programs for the return or destruction of unused opioids.[7] NACDS fully supports FDA's policy position and we applaud FDA for recognizing the supply chain team effort required for effective consumer controlled substance disposal. Accordingly, we urge the Subcommittee to also support FDA's policy position, as well.

Beyond the development and implementation of a variety of consumer controlled substance disposal programs, NACDS also supports patient education programs on consumer controlled substance disposal programs. To promote public awareness and use of the available disposal options, we encourage federal and state government and/or pharmaceutical

[7] "FDA Asks E&C For New Authority On Opioid Evaluation, Seizure; Suggests Requirements On Manufacturers;" *Inside Health Policy,* https://insidehealthpolicy.com/daily-news/fda-asks-ec-new-authority-opioid-evaluation-seizure-suggests-requirements-manufacturers, accessed February 9, 2018; Referencing FDA policy document provided to the House Energy and Commerce Committee.

manufacturer stewardship organizations to develop and provide drug disposal educational materials to consumers. Ideally, such materials should focus upon controlled substances, including the dangers of misuse and the potential for addiction to prescription controlled substances, treatment resources available, and the proper way to dispose of unused prescription controlled substances. These educational materials should be posted on government websites and be made available to pharmacies to provide to customers filling controlled substance prescriptions, with each pharmacy determining the best method for making those materials available to its patient population in a written and/or electronic format.

IV. 7-Day Supply Limit for Initial Opioid Prescriptions Issued for Acute Pain

NACDS supports policies establishing a 7-day supply limit for initial opioid prescriptions written for acute pain. This policy aligns with the *Guideline for Prescribing Opioids for Chronic Pain* developed by the Centers for Disease Control and Prevention (CDC) and serves to reduce the incidence of misuse, abuse, and overdose of these drugs.[8]

A clinical evidence review performed by the CDC revealed that a greater amount of early opioid exposure is associated with a greater risk for long-term use and addiction.[9] Notably, the average day supply per opioid prescription has increased in recent years, growing from 13.3 to 18.1 days per prescription between 2006 and 2016.[10] Considering this trend and the risk of early exposure to higher amounts of opioids, it is imperative that lawmakers adopt policies to promote careful prescribing practices for prescription opioids.

So far, over 20 states have adopted laws or other policies limiting the maximum day supply that can be authorized on an initial opioid prescription for acute pain (with appropriate exemptions, such as patients with pain due to cancer, hospice, or other end-of-life care, etc.)

Chain pharmacy encourages Congress to enact legislation that is standardized across the nation to promote consistent patient care and implementation across the country. NACDS would support federal legislation that preempts individual state variations.

- *Limiting Opioid Prescriptions*

  Health plans and their pharmacy benefit managers are also altering health plan designs to cover less than prescribed amounts of opioids. However, existing federal and state standards may complicate efforts by pharmacies to dispense less than prescribed amounts of opioids. Several states have laws or rules that can be read to require pharmacies to dispense medications as prescribed. Section 702 of the Comprehensive Addiction and Recovery Act of 2016 allows pharmacies to dispense less than prescribed amounts of opioids, but only as allowed by DEA rules or when "requested by the patient or the practitioner that wrote the

[8] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*. CDC.gov. https://www.cdc.gov/drugoverdose/prescribing/guideline.html.
[9] Ibid.
[10] Centers for Disease Control and Prevention, *Annual Surveillance Report of Drug-Related Risks and Outcomes*. United States, 2017. https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf

prescription." A DEA rule also raises questions regarding the ability of pharmacies to dispense less than prescribed amounts of opioids. The rule provides that a pharmacist may partially fill a prescription for a Schedule II opioid only if the pharmacist is "unable" to dispense the full amount prescribed.[11] NACDS and others have asked DEA to clarify when pharmacies may dispense less than prescribed amounts of opioids.

In the absence of DEA action to clarify these matters, NACDS would support federal legislation to clarify federal policy regarding when pharmacies may dispense less than prescribed amounts of opioids.

Practitioner Education

As the Subcommittee considers H.R. 2063, legislation to amend the Controlled Substances Act to require certain practitioner education as a condition of registration to prescribe or dispense opioids for the treatment of pain or pain management, we ask the Subcommittee to consider expanding this education requirement beyond opioids to include all controlled substances in Schedules II-V.

As currently drafted, H.R. 2063 requires that as a condition of obtaining and maintaining DEA registration, prescribers who prescribe or dispense opioids must complete twelve hours of continuing education on pain management treatment guidelines and best practices, early detection of opioid addiction, and the treatment and management of opioid-dependent patients. However, there are non-opioid controlled substance medications that can be abused individually, by their very nature, and/or concurrently with opioids as potentiators of the desired illicit effect (e.g., the so-called "Holy Trinity" of opioids, benzodiazepines, and carisoprodol).

Given that all controlled substances can potentially be abused as well as the increased risk of overdose with concurrent use of opioids and other controlled substances in particular, prescribers of all controlled substance medications should be educated on pain management treatment guidelines and best practices, early detection of controlled substance medication addiction, and the treatment and management of patients that are addicted to controlled substance medications.

Accordingly, NACDS recommends that H.R. 2063 be amended to ensure that all prescribers of controlled substances complete the required continuing education as a condition of maintaining their DEA registration.

Conclusion

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.

[11] 21 CFR §1306.13(a).